

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D0907183	<b>(X3) Date Survey Completed</b> 07/18/2023
<b>Name of Provider or Supplier</b> Bellin Hfmc Ashwaubenon	<b>Street Address, City, State</b> 1630 Commanche Ave, Green Bay, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2004</b>	<p>ENROLLMENT CFR(s): 493.801(a)(3)</p> <p>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records, federal Certification and Survey Provider Enhanced Reports (CASPER), and interview with the technical consultant, the laboratory changed PT programs after one of three hematology events in 2022 and did not participate in a single approved hematology proficiency testing program for one of the last three calendar years. Findings include: 1. Review of PT records for 2022 showed the laboratory participated in the College of American Pathologists (CAP) PT program for hematology in event one. Further review showed the laboratory participated in the Wisconsin State Laboratory of Hygiene PT program for hematology in events two and three. 2. Review of CASPER 155D 'Individual Laboratory Profile' report showed the laboratory received hematology PT results from CAP for the events in 2020 and 2021 and the first event in 2022 and received hematology PT results from WSLH for events two and three in 2022. 3. Interview with the technical consultant on July 18, 2023, at 9:45 AM confirmed the laboratory did not participate in a single approved hematology proficiency testing program for the full 2022 year before designating a different PT program for hematology.</p>
<b>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory</p>

is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:  
Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) and Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records, and interview with the technical consultant, the laboratory failed to participate successfully in PT for the cell identification or white blood cell (WBC) differential analyte in the specialty of hematology for two consecutive events of the last three events. Findings include: 1. The laboratory participated unsuccessfully in the WBC differential analyte in event three in 2022 and event one in 2023. See D2130.

**D2130**

**HEMATOLOGY**  
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) and Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) reports for hematology and interview with the technical consultant, the laboratory failed to perform satisfactorily in two consecutive events of the last three events for the cell identification / WBC (White Blood Cell) differential regulated analyte. Unsatisfactory performance for two out of three consecutive events is unsuccessful PT performance. Findings include: 1. Review of the CASPER 155D 'Individual Laboratory Profile' PT report showed the laboratory performed unsatisfactorily in two consecutive PT events for cell identification / WBC differential testing in the specialty of hematology in 2022. 2022 Event three, score 56% and 2023 Event one, score 60%. 2. Review of the WSLH PT evaluation reports confirmed the unsatisfactory PT scores for cell identification / WBC differential for the third event in 2022 and the first event in 2023. \*Event three 2022, Module 2290, Hematology - Comprehensive - AF5 The laboratory submitted unacceptable results for the percentage of neutrophils (40% score), lymphocytes (20% score), monocytes (60% score), and eosinophils (60% score). The combined score was 56% for the WBC differential. \*Event one 2023, Module 2290, Hematology - Comprehensive - AF5 The laboratory submitted unacceptable results for the percentage of neutrophils (60% score), lymphocytes (60% score), monocytes (60% score), eosinophils (60% score), and basophils (60% score). The combined score was 60% for the WBC differential. 3.

Interview with the technical consultant on July 18, 2023, at 9:45 AM confirmed the resulting 56% score for event three in 2022 and 60% score for event one in 2023 were unsatisfactory. Unsatisfactory performance for two consecutive events is unsuccessful PT performance.